

PATENT COOPERATION TREATY

PCT

INTERNATIONAL PRELIMINARY EXAMINATION REPORT

(PCT Article 36 and Rule 70)

REC'D 05 NOV 2001

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Applicant's or agent's file reference PC-2001575	FOR FURTHER ACTION See Notification of Transmittal of International Preliminary Examination Report (Form PCT/IPEA/416)	
International application No. PCT/SE00/01390	International filing date (day/month/year) 30.06.2000	Priority date (day/month/year) 06.07.1999
International Patent Classification (IPC) or national classification and IPC C07K 14/075, C12N 7/00, C12N 15/00		
Applicant Got-A-Gene et al		

1. This international preliminary examination report has been prepared by this International Preliminary Examining Authority and is transmitted to the applicant according to Article 36.
2. This REPORT consists of a total of 5 sheets, including this cover sheet.
- ☒ This report is also accompanied by ANNEXES, i.e., sheets of the description, claims and/or drawings which have been amended and are the basis for this report and/or sheets containing rectifications made before this Authority (see Rule 70.16 and Section 607 of the Administrative Instructions under the PCT).

These annexes consist of a total of 3 sheets.

3. This report contains indications relating to the following items:

- I ☒ Basis of the report
- II ☐ Priority
- III ☐ Non-establishment of opinion with regard to novelty, inventive step and industrial applicability
- IV ☒ Lack of unity of invention
- V ☒ Reasoned statement under Article 35(2) with regard to novelty, inventive step or industrial applicability; citations and explanations supporting such statement
- VI ☒ Certain documents cited
- VII ☐ Certain defects in the international application
- VIII ☐ Certain observations on the international application

Date of submission of the demand 06.02.2001	Date of completion of this report 24.10.2001
Name and mailing address of the IPEA/SE Patent- och registreringsverket Box 5085 S-102 42 STOCKHOLM Facsimile No. 08-667 72 88	Authorized officer Hampus Rystedt/BS Telephone No. 08-782 25 00

Form PCT/IPEA/409 (cover sheet) (January 1998)

INTERNATIONAL PRELIMINARY EXAMINATION REPORT

International application No.

PCT/SE00/01390

I. Basis of the report

1. With regard to the elements of the international application:*

- ☐ the international application as originally filed
- ☒ the description:
 pages 1-20, as originally filed
 pages _____, filed with the demand
 pages _____, filed with the letter of _____
- ☒ the claims:
 pages _____, as originally filed
 pages _____, as amended (together with any statement) under article 19
 pages _____, filed with the demand
 pages 21-23, filed with the letter of 04.10.2001
- ☒ the drawings:
 pages 1-5, as originally filed
 pages _____, filed with the demand
 pages _____, filed with the letter of _____
- ☒ the sequence listing part of the description:
 pages 1-12, as originally filed
 pages _____, filed with the demand
 pages _____, filed with the letter of _____

2. With regard to the language, all the elements marked above were available or furnished to this Authority in the language in which the international application was filed, unless otherwise indicated under this item.

These elements were available or furnished to this Authority in the following language _____ which is:

- ☐ the language of a translation furnished for the purposes of international search (under Rule 23.1(b)).
- ☐ the language of publication of the international application (under Rule 48.3(b)).
- ☐ the language of the translation furnished for the purposes of international preliminary examination (under Rules 55.2 and/or 55.3).

3. With regard to any nucleotide and/or amino acid sequence disclosed in the international application, the international preliminary examination was carried out on the basis of the sequence listing:

- ☐ contained in the international application in written form.
- ☐ filed together with the international application in computer readable form.
- ☐ furnished subsequently to this Authority in written form.
- ☐ furnished subsequently to this Authority in computer readable form.
- ☐ The statement that the subsequently furnished written sequence listing does not go beyond the disclosure in the international application as filed has been furnished.
- ☐ The statement that the information recorded in computer readable form is identical to the written sequence listing has been furnished.

4. ☐ The amendments have resulted in the cancellation of:

- ☐ the description, pages _____
- ☐ the claims, Nos. _____
- ☐ the drawings, sheet/fig _____

5. ☐ This report has been established as if (some of) the amendments had not been made, since they have been considered to go beyond the disclosure as filed, as indicated in the Supplemental Box (Rule 70.2 (c)).**

* Replacement sheets which have been furnished to the receiving Office in response to an invitation under Article 14 are referred to in this report as "originally filed" and are annexed to this report since they do not contain amendments (Rules 70.16 and 70.17).

** Any replacement sheet containing such amendments must be referred to under item I and annexed to this report.

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IV. Lack of unity of invention

1. In response to the invitation to restrict or pay additional fees the applicant has:

- ☐ restricted the claims.
- ☐ paid additional fees.
- ☐ paid additional fees under protest.
- ☐ neither restricted nor paid additional fees.

2. ☐ This Authority found that the requirement of unity of invention is not complied with and chose, according to Rule 68.1, not to invite the applicant to restrict or pay additional fees.

3. This Authority considers that the requirement of unity of invention in accordance with rules 13.1, 13.2 and 13.3 is

- ☐ complied with.
- ☒ not complied with for the following reasons:

In the application the following inventions have been found:

1. A recombinant adenovirus with modified tropism. The special technical feature of this invention is that the native knob containing the cell binding structure and the native trimerisation motif has been removed and a new cellbinding ligand and an external trimerisation motif has been introduced into the virus fiber. This invention is disclosed in claims 1-22.
2. A method in which the special technical feature is rescuing of recombinant adenovirus fibers into the adenovirus genome. This invention is disclosed in claim 23.

4. Consequently, the following parts of the international application were the subject of international preliminary examination in establishing this report:

- ☒ all parts.
- ☐ the parts relating to claims Nos. _____

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V. Reasoned statement under Article 35(2) with regard to novelty, inventive step or industrial applicability; citations and explanations supporting such statement

1. Statement

Novelty (N)	Claims	<u>1-22</u>	YES
	Claims		NO
Inventive step (IS)	Claims	<u>1-22</u>	YES
	Claims		NO
Industrial applicability (IA)	Claims	<u>1-22</u>	YES
	Claims		NO

2. Citations and explanations (Rule 70.7)

The following documents are considered relevant:

D1: WO-A2-9720051

D2: WO-A1-9626281

Through D1 (see esp. abstract; page 7 lines 7-17; page 11 line 22-page 13 line 16; page 14 line 22-page 17 line 22; page 33 line 31-page 34 line 17; page 77 lines 1-9) a genetically modified adenovirus with a chimeric surface protein is known. The virus is intended for use in gene therapy. D1 states that a recombinant adenovirus with a chimeric fiber protein can be constructed through replacement of the native knob region, which contains the receptor binding structure and trimerisation domain, with a non-native trimerisation domain.

D2 describes methods for constructing recombinant adenoviruses in which the native knob region, comprising receptor-binding and trimerisation domains, is replaced with a non-native trimerisation domain and a protein-specific binding domain, see page 16 lines 1-6.

Neither D1 or D2 mentions the possibility of introducing cell-binding domains in the shaft region of the fiber protein. Claims 1-21 are therefore novel. Since the shaft region can tolerate larger inserts than the knob region, and consequently allows for more varied inserts, the recombinant adenovirus of claims 1-21 is considered to possess inventive step; they are also considered to be industrially applicable.

The method according to claim 22 is a very specific method for producing recombinant adenoviruses. It is novel and also considered to possess inventive step and industrial applicability.

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VI. Certain documents cited

1. Certain published documents (Rule 70.10)

Application No. Patent No.	Publication date (day/month/year)	Filing date (day/month/year)	Priority date (valid claim) (day/month/year)
WO 9941359	19.08.1999	16.02.1999	17.02.1998

2. Non-written disclosures (Rule 70.9)

Kind of non-written disclosure	Date of non-written disclosure (day/month/year)	Date of written disclosure referring to non-written disclosure (day/month/year)